

## ALLERGY AND ADVERSE DRUG REACTION (ADR) DEFINITIONS

### DEFINITIONS

**Adverse drug reaction (ADR):** "A response to a drug which is noxious and unintended, and which occurs at doses normally used or tested in man for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function". *World Health Organization*

**Table: ADR Category with definitions**

<i>iPM categories</i>	<i>Definition</i>	<i>Example</i>
<b>Allergy</b> (Unpredictable)	Adverse reaction occurring in a susceptible patient involving an <u>immunological</u> mechanism	<ul style="list-style-type: none"> <li>• <i>Penicillin anaphylaxis</i></li> <li>• <i>Steven's Johnson syndrome or TEN due to eg sulfonamide</i></li> <li>• <i>Cefaclor serum-sickness like reaction</i></li> </ul>
<b>Side effect</b> (Predictable, dose-related)	Any unintended effect of a pharmaceutical product, occurring at doses normally used and is related to the pharmacological properties of a drug	<ul style="list-style-type: none"> <li>• <i>Augmentin causing diarrhoea</i></li> <li>• <i>Anticholinergic causing dry mouth</i></li> <li>• <i>Cytotoxic causing nausea</i></li> </ul>
<b>Drug interaction</b> (Predictable, dose-related)	Interaction with another medicine causing variation in its metabolism or pharmacological effect. May increase or decrease a medicine's effects	<ul style="list-style-type: none"> <li>• <i>Increased cyclosporin levels (+/- toxicity) when taking erythromycin</i></li> <li>• <i>Decreased cyclosporin levels when taking carbamazepine</i></li> </ul>
<b>Intolerance</b> (Unpredictable)	A lower threshold to the normal pharmacologic action of a drug	<ul style="list-style-type: none"> <li>• <i>Tinnitus after a single average dose of aspirin</i></li> </ul>
<b>Toxicity/overdose</b> (Predictable, dose-related)  <i>Only unintentional overdoses are classified as ADRs i.e. due to error</i>	Always dose-related and usually occurs by the same mechanism as the therapeutic effect	<ul style="list-style-type: none"> <li>• <i>Morphine-induced sedation/respiratory depression</i></li> <li>• <i>Paracetamol overdose causing liver toxicity</i></li> <li>• <i>Seizure from excessive lignocaine</i></li> </ul>
<b>Idiosyncratic</b> (Unpredictable)	Adverse reaction occurring in susceptible patients. Mechanism usually unknown	<ul style="list-style-type: none"> <li>• <i>Anticonvulsant hypersensitivity</i></li> <li>• <i>Haemolytic anaemia due to G6PD deficiency</i></li> </ul>
<b>Other</b>	<b>Pseudo-allergic</b> reaction (resemble allergic reaction clinically but mechanism <u>not immunological</u> )	<ul style="list-style-type: none"> <li>• <i>Vancomycin red man syndrome</i></li> <li>• <i>Ampicillin rash with viral illness (vs true ampicillin allergy)</i></li> <li>• <i>Morphine itch</i></li> <li>• <i>Reaction to radio-contrast media</i></li> </ul>
	<b>Long-term drug effects</b> <ul style="list-style-type: none"> <li>• chronic use</li> <li>• latent or delayed effects</li> </ul>	<ul style="list-style-type: none"> <li>• <i>Growth suppression secondary to chronic steroid use</i></li> <li>• <i>Second malignancy after cancer chemotherapy</i></li> </ul>

**Members of the SCH Working Party; November 2006**

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